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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *3,24 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,4-23 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/1/04, 7/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, drawn to a medical device, classified in class 604, subclass 523.

II. Claims 33-37, drawn to a method of making a catheter tip, classified in class 265, subclass 320.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a process other than reflowing can make the catheter tip.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Species A: Figs. 1 and 2

Species B: Figs. 3 and 4

Species C: Fig. 5

Species D: Fig. 6

The species are independent or distinct because each species is a different embodiment of a catheter tip.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 9, 25 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Mr. Glenn Seager on 5/3/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-32 and Species B, Figs. 3 and 4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 24 and 29-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "wire", "coil" and "anchoring sites" in claims 13-15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: page 1, line 12 should have the word "distally" changed to "distal". Also in page 1, line 15, the word "engage" should be changed to "engaged". Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: "the tip have" should be changed to "the tip having".

Claim 26 is objected to because of the following informalities: "tapers distal" should be changed to "tapers distally". Appropriate correction is required.

Claims 1, for example, is objected to because of the following informalities: "distal the first position" lacks a proper preposition between "distal" and the first position. The examiner has found numerous cases of these omitted prepositions after the words "distal" and "proximal". Appropriate correction is required in all claims affected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "the catheter tube" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the first diameter" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner what the end of the phrase "both at the first outer diameter" when followed by the previous wording is trying to claim. It would appear that "both ..." should be changed to some type of phrase such as "both having the a diameter equal to the first outer diameter", however, this claim is quite unclear to the examiner in its scope and intent and correction and explanation is requested. Furthermore, it is unclear claim 22 can proceed to claim "the third outer diameter" when there is no "third outer diameter" mentioned previously in this claim.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner in what is meant by "the second region is a radius". Does the applicant intend that the region is circular and has a radius? Appropriate correction and explanation are requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Tassel et al. (US Patent No. 4,531,943).

Van Tassel discloses a medical device, comprising: an elongate catheter (Figs. 4 and 5) having a proximal end (10), a distal end (26), and a lumen (11) extending therethrough; and a tip (28) disposed at the distal end of the elongate catheter, the tip extending distally of the distal end of the catheter, the tip comprising a soft body portion (24, also see col. 4, line 40 through col. 5, line 7) and a rigid ring (30) distal the soft body portion (see col. 5, lines 2-7).

Van Tassel further discloses a medical device, comprising: an elongate catheter (Figs. 4 and 5) having a proximal end (10), a distal end (26), and a lumen (11) extending therethrough; a tip (28) disposed at the distal end of the elongate catheter having a first region (27) that tapers distally and a second region (25) distal the first region that tapers distally more sharply than the first region. Van Tassel further discloses that the second region (25) is the distal-most portion of the tip, and that the second region can be defined as circular with a radius.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 5, 8-12, 15-18, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. (US Patent No. 4,531,943) in view of Nash et al. (US Patent No. 6,080,170).

Van Tassel discloses the device substantially as claimed including: a medical device comprising: an elongate tubular member (Figs. 4 and 5) having a proximal end (10) and a distal end (26), a tip (28) disposed at the distal end of the elongate tubular member, the tip having a first portion (27) having a distal taper and a radially inextensible ring (30) distal to the first portion (col. 4, line 40 through col. 5 line 7). Van Tassel further discloses a balloon (Fig. 2, 15) as a therapeutic device disposed on the distal portion of the catheter tube. Van Tassel further discloses that the first portion (24) is softer and more flexible than a proximal portion of the medical device (col. 1, line 65 through col. 2, line 9). Van Tassel further discloses that the ring (30) is the distal-most portion of the tip (Fig. 4), and that the device is an intravascular guide catheter (col. 2, lines 57-69 disclose that this catheter is for use in the vascular system and that it is to be guided to a predetermined location before use).

Van Tassel further discloses a medical device comprising: an elongate tubular member (Figs. 4 and 5) having a proximal end (10) and a distal end (26), a tip (28)

disposed at a distal end of the elongate tubular member and having a distal end (25), a proximal end (28) and a lumen (11) therethrough, the tip having an elastic portion (24) and a radially inextensible distal portion (30, also see col. 4, line 40 through col. 5, line 7). Van Tassel further discloses that the distal portion (30) is a distal-most extremity (Figs. 4 and 5). Van Tassel further discloses that the distal portion comprises a ring having a lumen therethrough. In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Nash.

Van Tassel further discloses that the tip further comprises a flexible portion (between 28 and 30) proximate the distal portion (30). Van Tassel also discloses that the distal portion is a distal-most extremity and the flexible portion is proximal the distal portion, wherein the flexible portion tapers from a first outer diameter (diameter at 27) to a second outer diameter (diameter to the left of 30), which is less than the first outer diameter. Van Tassel further discloses that the first outer diameter and inner diameter (at 27) has a first thickness, and a distal thickness (located just to the left of 30, where the soft tip (24) is still surrounding part of (30), this location has a much smaller thickness of the material used in the rest of the tip and also has a smaller outer diameter than the outer diameter at (27)) at a third outer diameter distal the first outer diameter, wherein the distal thickness is less than the thickness at the first outer and inner diameter. Van Tassel further discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and second plane normal to the first plane (Fig. 4 shows the inner surface at (27) is concave).

Van Tassel, however, does not disclose a guidewire, and the particular embodiment of Van Tassel being used does not comprise a therapeutic device. Van Tassel, does however in a different embodiment, disclose a therapeutic device, a balloon catheter (15) in Fig. 2 on the distal portion of the catheter tube. Nash discloses a guidewire (Fig. 10, 124) having a first diameter and a distal stop (190) having a second diameter greater than the first diameter, and a medical device comprising: an elongate tubular member (22") having a proximal end and a distal end with a guide wire receiving lumen extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter. Nash further discloses that the medical device is an angioplasty device. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Van Tassel's embodiment in Figs. 4 and 5, with the balloon of Fig. 2, and also to have modified Van Tassel with the guide wire as taught by Nash. This would have been especially obvious since using a guidewire in a lumen of a catheter is exceptionally well known in the art. This modification would provide the catheter of Van Tassel with a balloon for therapeutic use and also would provide the catheter with a guidewire in order to provide the catheter with a steering mechanism.

Claims 13, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel in view of Nash, and further in view of Sleiman (US Patent No. 4,738,659). Van Tassel in view of Nash discloses the device substantially as claimed except for the distal portion being comprised of a wire, coiled wire, band, or the distal portion having anchoring sites. Sleiman, however, discloses that the distal portion of a

catheter tip (Fig. 2) comprises a wire, or a coiled wire (Figs. 5 and 6, also see col. 2, lines 62-68). Sleiman further discloses that distal portion comprises a non-compliant band (Figs. 7 and 8, 46; also see col. 3, lines 28-32 which describes that the band is unable to stretch and see col. 2, lines 62-67 which indicates that it would have been obvious to make this band of plastic, as the other reinforcement devices can be made of plastic). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Van Tassel in view of Nash with the wire, coiled wire and band as taught by Sleiman, in order to provide alternative structures to use as the distal portion of the tip of the catheter for further variety.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS

LCS

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons
5/11/06